

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

CHRISTINA RENFROE,)	
)	
Plaintiff,)	
)	
v.)	1:20CV362
)	
ETHICON, INC. and)	
JOHNSON & JOHNSON,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

LORETTA C. BIGGS, District Judge.

Plaintiff Christina Renfroe initiated this action in April 2020 alleging multiple violations of North Carolina statutory and common law arising from injuries she suffered as a result of the implantation of pelvic mesh products that were designed, manufactured, and marketed by Defendants Ethicon, Inc. and Johnson & Johnson. (ECF No. 1.) Before the Court is Defendants’ Partial Motion to Dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (ECF No. 8.) For the reasons stated below, the Court grants Defendants’ motion in part and denies it in part.

I. BACKGROUND

According to Plaintiff, Defendants have marketed and sold pelvic mesh products that are designed to treat “medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence,” since at least 2002. (ECF No. 1 ¶¶ 13–19.) In March 2017, one of these products was implanted in Plaintiff, and she alleges that, as a result, she “has

experienced significant mental and physical pain and suffering, has sustained permanent injury and permanent and substantial physical deformity[,] and has suffered financial or economic loss.” (*Id.* ¶¶ 20, 23.) Plaintiff contends that her experience is not an outlier but rather that these products have “high failure, injury, and complication rates.” (*Id.* ¶ 26.) Nevertheless, according to Plaintiff, Defendants have suppressed information related to their products’ performance, have failed to perform adequate testing, have failed to design a safe and effective procedure for product removal, and have declined to provide adequate training and information to physicians implanting such products. (*Id.* ¶¶ 27, 28, 29, 30, 33.)

On these allegations, Plaintiff originally brought eleven counts before the Court. (*Id.* ¶¶ 37–148.) These include: a failure to warn; negligence; negligent misrepresentation; design defect; manufacturing defect; breach of express and implied warranty; violation of the North Carolina Consumer Protection and Deceptive Business Practices Act; fraud; fraud by concealment; and punitive damages. (*Id.*) Defendants now move to dismiss eight of these claims, (ECF Nos. 8 at 1–2; 9 at 1), and Plaintiff has declined to oppose the dismissal of four counts,¹ (ECF No. 10 at 1 n.1). Accordingly, there are only four counts to be considered by the Court at this time: Count I (a failure to warn); Count II (negligence); Count V (manufacturing defect); and Count VII (breach of implied warranty). The parties agree that each of these claims are governed by North Carolina law. (*See* ECF Nos. 9 at 3–4; 10 at 2 n.2.)

¹ The Counts that Plaintiffs concede are Count III (negligent misrepresentation), Count VI (breach of express warranty), Count IX (fraud), and Count X (fraud by concealment). (ECF No. 10 at 1 n.1.)

II. STANDARD OF REVIEW

A motion to dismiss under Rule 12(b)(6) “challenges the legal sufficiency of a complaint,” including whether it meets the pleading standard of Rule 8(a)(2). *See Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009). Rule 8(a)(2) requires a complaint to contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed. R. Civ. P. 8(a)(2), thereby “giv[ing] the defendant fair notice of what the . . . claim is and the grounds upon which it rests,” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). To survive a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). In assessing a claim’s plausibility, a court must draw all reasonable inferences in the plaintiff’s favor. *Vitol, S.A. v. Primerose Shipping Co.*, 708 F.3d 527, 539 (4th Cir. 2013).

A claim is plausible when the complaint alleges facts that allow the court “to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. However, “mere conclusory and speculative allegations” are insufficient, *Painter’s Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013), and a court “need not accept as true unwarranted inferences, unreasonable conclusions, or arguments,” *Vitol*, 708 F.3d at 548 (quoting *Jordan v. Alt. Res. Corp.*, 458 F.3d 332, 338 (4th Cir. 2006)). A complaint may fail to state a claim upon which relief can be granted in two ways: first, by failing to state a valid legal cause of action, *i.e.*, a cognizable claim, *see Holloway v. Pagan River Dockside Seafood, Inc.*, 669 F.3d 448, 452 (4th Cir. 2012); or second, by failing to allege sufficient facts to support a legal cause of action, *see Painter’s Mill Grille*, 716 F.3d at 350.

III. DISCUSSION

1. *Failure to Warn (Count I)*

Plaintiff first alleges that “Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants’ Pelvic Mesh Product.” (ECF No. 1 ¶ 38.) Under North Carolina law, “[n]o manufacturer or seller of a product shall be held liable . . . for a claim based upon inadequate warning or instruction” unless three elements are satisfied. *See* N.C. Gen. Stat. § 99B-5(a). First, a plaintiff must show that the defendant “acted unreasonably in failing to provide such warning or instruction.” *Id.* Second, the lack of adequate warning must have been “a proximate cause of the harm for which damages are sought.” *Id.* Third, the defendant must or should have known that, absent a warning, its product “created an unreasonably dangerous condition . . . to a reasonably foreseeable claimant.” *Id.* Alternatively, this final element may be satisfied if a defendant became aware of the risk and nevertheless “failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.” *Id.*

Here, Plaintiff alleges each of these elements. First, she claims that Defendants were unreasonable in failing to provide such a warning given their “inadequate research and testing” of the products and “the complete lack of a safe, effective procedure for [their] removal.” (ECF No. 1 ¶ 40.) Second, she alleges that she has been injured” in multiple ways “[a]s a proximate result of Defendants’ design, manufacture, marketing, sale, and distribution” of the products. (*Id.* ¶ 43.) Third, and finally, Plaintiff alleges that Defendants “intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits” of these products,

thereby creating an unreasonably dangerous situation for those who would be implanted with such products. (*Id.* ¶ 42.)

Though Defendants object to Plaintiff's use of the phrase "strictly liable," (*see* ECF No. 9 at 4 (citing ECF No. 1 ¶ 44)), Plaintiff nevertheless states her claim with sufficiency to survive a motion to dismiss that does not depend upon a theory of strict liability. Accordingly, the Court denies Defendants' motion with regards to Count I.

2. *Negligence (Count II)*

"To state a common law negligence claim [in North Carolina], [a] plaintiff must show (1) a legal duty; (2) a breach thereof; and (3) injury proximately caused by the breach." *Bridges v. Parrish*, 742 S.E.2d 794, 796 (N.C. 2013) (citation and internal quotation marks omitted). Here, Plaintiff claims that that "Defendants had a duty to exercise reasonable and ordinary care in the manufacture, labeling, instructions, warning, sale, marketing, and distribution" of the products at issue. (ECF No. 1 ¶ 46.) She further alleges that Defendants breached that duty when they "under-reported, underestimated[,] and downplayed the serious dangers" of those products. (*Id.* ¶ 48.) Finally, she contends that "[a]s a proximate result" of this breach, she "has been injured" in several ways. (*Id.* ¶ 51.)

Defendants argue only that "Plaintiff vaguely alleges that 'Defendants breached their duty of care to the Plaintiff . . . in the manufacture . . . [of] the Pelvic Mesh Product.'" (ECF No. 9 at 5 (citing ECF No. 1 ¶ 47) (alterations in the original).) This contention ignores the totality of Plaintiff's allegations, and the Court finds that the assertions discussed above state a plausible claim to relief sufficient to withstand a motion to dismiss. Accordingly, the Court denies the motion to dismiss Plaintiff's negligence claim.

3. *Manufacturing Defect (Count V)*

To establish a product liability claim in North Carolina, a plaintiff must demonstrate that “(1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant’s negligence, and (3) the defect proximately caused plaintiff’s damage.” *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.*, 540 S.E.2d 321, 326 (N.C. Ct. App. 2000). Here, Plaintiff has alleged that the products “implanted in Plaintiff were not reasonably safe at the time [they] left control of the Defendants.” (ECF No. 1 ¶ 78.) As discussed in more detail above, Plaintiff has also sufficiently alleged that the defect was the result of negligence on the part of Defendants. (*See, e.g.*, ECF No. 1 ¶ 29 (“Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants’ Pelvic Mesh Product.”) Further, Plaintiff alleges that she has been injured “[a]s a proximate result of Defendants’ conduct.” (*Id.* ¶ 79.)

Defendants take issue with what they call “bare legal conclusions” with “absolutely no factual support,” (ECF No. 9 at 5), yet this argument ignores the comprehensive set of facts alleged throughout the Complaint that this count incorporates. As discussed above, Plaintiff has contended that the product defects caused harm in multiple ways, and these allegations are sufficient to state a plausible claim under federal pleading standards. (*See, e.g.*, ECF No. 1 ¶¶ 34–35 (noting that the product “implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants” and that Plaintiff subsequently suffered “mesh erosion, mesh contraction, infection,” and several other serious injuries following implantation).) Accordingly, the Court denies Defendants’ motion to dismiss with regards to Plaintiff’s manufacturing defect claim.

4. *Breach of Implied Warranty (Count VII)*

The final count that Defendants move to dismiss is the breach of implied warranty. They challenge this claim in two ways. First, they contend that it “should be dismissed for lack of pre-suit notice.” (ECF No. 9 at 6.) In support of this claim, Defendants point to a North Carolina statute which states that a plaintiff asserting a claim for breach of warranty “must within a reasonable time after [s]he discovers or should have discovered the breach notify the seller of the breach or be barred from any remedy.” (*Id.* (citing N.C. Gen. Stat. § 25-2-607(3)(a)).) Further, Defendants contend that “Plaintiff does not allege that she provided Defendants notice of the alleged breach of warranty prior to filing the instant action, and thus, her [implied warranty claim] must be dismissed.” (*Id.*) However, as Plaintiff points out, “when the plaintiff is a lay consumer and notification is given to the defendant by the filing of an action within the period of the statute of limitations,” this requirement is satisfied. *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 786 (W.D.N.C. 2008) (quoting *Maybank v. S.S. Kresge Co.*, 273 S.E.2d 681, 685 (N.C. 1981)). Accordingly, the Court finds that Plaintiff has satisfied the requirements of notice under North Carolina law.

Next, Defendants argue that the breach of implied warranty of fitness for a particular purpose “fails because it is undisputed that [the product] was sold and implanted for its ordinary purpose—to treat urinary incontinence.” (ECF No. 9 at 7 (citing ECF No. 1 ¶ 103).) Under North Carolina law, when a “seller at the time of contracting has reason to know any particular purpose for which the goods are required and the buyer is relying on the seller’s skill or judgment to select or furnish goods,” there is “an implied warranty that the goods shall be fit for such purpose.” N.C. Gen. Stat. § 25-2-315. That said, “ordinary, intended use prevents

recovery under the implied warranty of fitness for a particular purpose as a matter of law.” *McDonald Bros., Inc. v. Tinder Wholesale, LLC*, 395 F. Supp. 2d 255, 266 (M.D.N.C. 2005) (citing *Halprin v. Ford Motor Co.*, 420 S.E.2d 686, 691 (N.C. Ct. App. 1992)).

Here, Plaintiff does not allege that the use of the products at issue were anything other than what was originally intended by Defendants. Though she has certainly relied on their expertise, such a claim more readily falls under a theory of an implied warranty of merchantability, which Plaintiff has also claimed under the same count. (See ECF Nos. 1 ¶ 97 (“Defendants impliedly warranted the product to be of merchantable quality, safe[,] and fit for such use.”); 10 at 7 n.3 (“Count VII of Plaintiff’s Complaint asserts claims for breach of implied warranty of fitness for a particular purpose and breach of implied warranty of merchantability.”).) Accordingly, Defendants’ Motion to Dismiss with regards to Count VII is granted as to Plaintiff’s claim of implied warranty of fitness for a particular purpose only, and it is denied as to any other claim in that count.

For these reasons, the Court enters the following:

ORDER

IT IS THEREFORE ORDERED that Defendants’ Rule 12(b)(6) Partial Motion to Dismiss, (ECF No. 8), is GRANTED IN PART AND DENIED IN PART.

The motion is GRANTED with respect to Counts III, VI, IX, and X. Those claims are hereby DISMISSED WITH PREJUDICE.

The motion is further GRANTED with respect to Count VII only as to the claim of implied warranty of fitness for a particular purpose, however it is DENIED as to all other claims in that Count.

The motion is additionally DENIED with respect to Counts I, II, and V.

This, the 30th day of March 2021.

/s/ Loretta C. Biggs
United States District Judge